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EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/30/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,982	LEHMAN ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 May 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10, 12-16 and 18-40 is/are pending in the application.

4a) Of the above claim(s) 32-39 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10, 12-31 and 40 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Claims 1-10, 12-16, and 18-40 are pending.

The instant application is a CIP of case serial no. 09/671,943, filed September 27, 2000, and is now US Patent No. 6,524,577. Applicants' reference to the CIP at page 1, line 1, of the instantly filed specification is noted, however, Applicants are directed to update the status at page 1, line 1, of the instant specification with respect to the current status of the parent CIP application, wherein the amendment --, now U.S. Patent No. 6,524,577—should be added after “filed September 27, 2000” at page 1, line 6 of the instant application.

The petition filed under 37 CFR 1.47 (A) and extension of time and drawings of April 17, 2002 are noted. Further, the change of address and associate power of attorney filed February 19, 2003, are also noted and acknowledged. In addition the revocation and new power of attorney filed March 13, 2003, are further acknowledged.

Also Applicants' extension of time to file an amendment and response to the restriction requirement, both filed May 2, 2003, are all received.

Applicant's election with traverse of Group I in Paper No. 13 is acknowledged. The traversal is on the ground(s) that there is no serious burden of search because Group II is directed to a product and thus, found within the same classification as Group I, and because of the sections of MPEP 2113 regarding product and product by process claims. This is not found persuasive because there is a serious burden of search for the examiner in that each of the process steps of Group II are required to be searched, and

these same process steps are not required steps of the product produced in Group I. Different classes and subclasses are required to be searched for these process steps of which the product by process requires. The restriction is based upon the fact that a serious burden of searching is required by the examiner to search for the process required of Group II to make the product of Group II. Two way distinctness is found between the products of Group I and Group II in that a specific set of process steps are required of Group II which are not required of Group I, thus, Group I is distinguishable from Group II in that different process steps may be employed for producing the product of Group I, and vice versa for the product of Group II. A serious burden of search for the examiner is presented by these two Groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 32-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims (Group II), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Claim Objections

Claim 16 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend from another claim in the alternative form only. See MPEP § 608.01(n). Accordingly, the claim 16, should have –one—inserted between “any” and “of” at line 1, of claim 16.

Also claim 31 should have —one— inserted at line 2 after “than” and before “metabolite”, in order to be consistent with other claims, this is being treated as a typo error in that the term —one— was most likely inadvertently left out by accident.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. It is noted that applicants have

deposited the organism but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

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(1) The name and address of the depository; (2) The name and address of the depositor; (3) The date of deposit;
(4) The identity of the deposit and the accession number given by the depository;
(5) The date of the viability test; (6) The procedures used to obtain a sample if the test is not done by the depository; and
(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:
(1) The accession number for the deposit;
(2) The date of the deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
(4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-31 and 40 are rendered vague and indefinite for failing to clearly recite that the strain has been biologically purified. Thus, --biologically pure—should be inserted before "Streptomyces sp. strain" at line 1 of claim 1 and at first occurrence at line 1 of claim 40, respectfully.

Claim 2 is rendered vague and indefinite for the recitation of "about 925 and about 865" wherein it is suggested to switch placement of the upper and lower ranges, respectively within this phrase since the lower range should come before the upper range. Further, the claims 2-10, 12-16, and 18-31 are rendered vague and indefinite

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since it is unclear what units of molecular weight are intended in the claim, perhaps Daltons, but this is not certain in the claims.

Claim 4 is redundant with respect to the molecular weight being repeated again, and it is suggested to change dependency from claim 1 to claim 2. Further in claims 2-10, 12-16 and 18-31 are rendered vague and indefinite when alternatively dependent upon claim 40, wherein the term "metabolite" lacks antecedent basis. Also claim 5 is redundant as well and should be canceled.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 12-14, 16, 18-19 and 40 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-5 and 11-12 of prior U.S. Patent No. 6,524,577. This is a double patenting rejection.

The instant claims 12-14, 16, 18-19 and 40 are no different than the patented claims 1, 3-5 and 11-12 wherein the instant claims are directed to the strain as well as are the patented strains and thus, this a true double patenting rejection because there is no significant difference between the claims. Applicants can not claim equivalent

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inventions in two separate patents *or in a single patent*. Instant claims alternatively depend from claim 40 which is the strain as claimed in claim 1 of the cited patent.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12-16, 18-31 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,524,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is not difference in scope between the claims.

It would have been obvious to one of ordinary skill in the art to select for a metabolite whether or not it is soluble in butanol, however, both metabolites are most probably. Therefore, at the time the patented claims would have made obvious the claims of the pending instant application. Thus, the claims are *prima facie* obvious over the patented claims.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 12-16, 18-31 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Breinholt et al. (A).

Claims are drawn to a metabolite and strain of *Streptomyces* and methods as well as compositions therefore.

Breinholt et al teach metabolite and strain of Streptomyces and methods as well as compositions therefore. Note abstract, column 3, lines 55-67, column 4, all lines, column 7, lines 1-15, columns 8-9, all lines, column 12, all lines, and column 13, lines 1-40.

The claims are identical to the disclosure of Breinholt et al. and are therefore, considered to be anticipated by the cited reference. However, in the alternative that there is some unidentified claim characteristic for which to provide for some difference between the two (claims and cited reference) then such difference is considered to be so slight as to render the claims obvious therefore. Thus, it would have been obvious for one of skill to select for a metabolite from Streptomyces strain of cited prior art reference with the expectation of success in that the same is disclosed by the cited prior art. One of skill would have expected if not an identical metabolite then one being so similar to the cited disclosure as to render the claims alternatively obvious therefrom. Thus, in the alterantive the claims are at least *prima facie* obvious over the cited reference. All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected. The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

Deborah K. Ware
DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
July 28, 2003